UNITED STATES PATENT AND TRADEMARK OFFICE

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10/684,708	10/15/2003	Hideya Takeo	Q77911	3651

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

	Application No.	Applicant(s)
Office Action Summary	10/684,708	TAKEO ET AL.
	Examiner	Art Unit	
	SEAN MOTSINGER	2624	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE <u>3</u> MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.
- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
  Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on <u>21 December 2007</u>.
2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.
3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) <u>1-24</u> is/are pending in the application.
   4a) Of the above claim(s) _____ is/are withdrawn from consideration.
5)☒ Claim(s) <u>21-24</u> is/are allowed.
6)☒ Claim(s) <u>1-20</u> is/are rejected.
7)☐ Claim(s) _____ is/are objected to.
8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.
10)☒ The drawing(s) filed on <u>15 October 2003</u> is/are: a)☒ accepted or b)☐ objected to by the Examiner.
   Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
   Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
   a)☒ All b)☐ Some * c)☐ None of:
      1.☒ Certified copies of the priority documents have been received.
      2.☐ Certified copies of the priority documents have been received in Application No. _____.
      3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
   * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1)☐ Notice of References Cited (PTO-892)
2)☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3)☐ Information Disclosure Statement(s) (PTO/SB/08)
   Paper No(s)/Mail Date _____.

4)☐ Interview Summary (PTO-413)
   Paper No(s)/Mail Date. _____.
5)☐ Notice of Informal Patent Application
6)☐ Other: _____.

Response to Applicants Arguments and Amendments

1.   Applicants arguments/amendments filed on 12/21/2007 have been entered and
made of record.

2.   Applicants Substitute specification filed in an amendment after final rejection filed
on 11/21/2007 (previously not entered) is now being entered and made of record as
of this office action.

3.   Regarding the objections to the claims, the claims have been cancelled and
therefore the rejection is moot.

4.   Regarding the objection to the specification. The examiner has entered the
previously filed substitute specification (as noted above). In light of this amendment
the examiner considers the objection to the specification overcome.

5.   Regarding the rejections under 35 U.S.C. 112 first and second paragraph with
respect to claims 29 and 30; these claims have been cancelled and are therefore
moot.

6.   Regarding the rejection under claims 35 U.S.C. 112 second paragraph with
respect to claims 7-12, 17-20, 23-24 applicants arguments have been considred and
found persuasive. In light of applicant's arguments and the MPEP section 2181

which states "Clearly, a unit which receives digital data, performs complex

mathematical computations and outputs the results to a display must be

implemented by or on a general or special purpose computer (although it is not clear

why the written description does not simply state computer or some equivalent

phrase)".

7.   Regarding the rejections Under 35 U.S.C. 102 with respect to claims 13-16 and

17-20 applicants arguments have been considered but are not found persuasive.

First of all the examiner would like to note that claims 13 and 17 are substantially

different from claims 1 and 7. For example claims 13 and 17 do not contain the

features argued in applicant's arguments on page 16. Therefore the rejections to

claims 13 and 17 have no applicable arguments and are maintained.

8.   Regarding the rejections under 35 U.S.C. 102 with respect to claims 1-12

applicant states that the ANN of Nishikawa is not linear and therefore does not meet

the limiation "using linear combination." While applicant is correct that the ANN of

Nishikawa does not appear to be linear (see paragraph 75) The examiner notes that

Nishiwaka states that his neural network can be replaced by a linear system such as

linear discriminate analysis.

9.   Regarding applicants arguments to the rejections under 35 U.S.C. 103 applicant

states that neither Cothren or nor Takeo discloses displaying the probability together

with the information for specifying the position of the detected abnormal pattern
candidate. However applicant is arguing the references separately and does
consider them in combination Takeo discloses displaying position information of the
abnormal pattern candidate alongside information regarding the degree of certainty
(confidence figure 12 B) in malignancy see figures 12 A and 12 B . While it does not
disclose displaying the degree of malignancy which is based on clinical results
Cothren discloses creating and displaying a degree of certainty based on clinical
results and displaying it (see rejection below).

10.   Regarding applicants argument that the claims amendment "linear combination"
is not new matter applicants argument has been considered but not found
persuasive. The examiner notes that applicant creates a plurality of indices
(commonly called a feature vector). Applicant then measures the Mahalanobis
distance between the feature vector and a vector representative of a cancerous
region and a vector representative of a non cancerous region. The examiner does
not understand the Mahalanobis distance to be linear because it is calculated with
square roots and powers of two. Then a liklihood ratio is created by dividing one of
these by the other. Examiner notes that this dividing step is non-linear. Furthermore
this method does have issues with singularities contrary to statements on page 16
because if distance which is the divisor rounds to zero clearly this division will result
in a singularity. Also just because a system in non-linear does not mean it can
contain singularities it depends upon the system. Therefore there does not appear to

be support in the specification as originally filed for a "single index value, which is

obtained using linear combination of a plurality of indices" because the method of

combining appears to have not only one but two non-linear steps.

Rejections Under 35 U.S.C. 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that

form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public
use or on sale in this country, more than one year prior to the date of application for patent in the United
States.

11.   Claims 13 - 20 rejected under 35 U.S.C. 102(b) as being anticipated by

Nishikawa US 6,058,332.

12.   Re Claim 13, Nishikawa discloses, An abnormal pattern candidate detection

processing method, comprising the steps of: i) detecting an abnormal pattern

candidate, which is embedded in a medical image, in accordance with a medical

image signal representing a medical image(see abstract), and ii) outputting at least

information for specifying the detected abnormal pattern candidate (see abstract),

wherein the method further comprises the step of selecting an arbitrary region in the

medical image (see column 18 lines 25-35 and column 36 lines60-65.) Note that the
system defines regions which define clusters which are described as arbitrary.
Calculating a degree of certainty about malignancy (i.e. likelihood of malignancy),
which degree represents a level of possibility of a pattern being a malignant pattern,
with respect to a pattern embedded in the selected region (see column 33 lines 13-
25.) Note that the system calculates the malignancy for the features including the
ones in the arbitrary region. The calculation being made in accordance with an index
value (i.e. ANN output) representing a feature of the pattern embedded in the
selected region and in accordance with a correlation between the index value and
possibility of a pattern being a malignant pattern (see column 33 lines 13-25), which
correlation has been obtained from clinical results (see column 33 lines 13-25.) Note
the correlation depends on the probability distribution of malignant and benign
cases. The step of outputting at least the information for specifying the detected
abnormal pattern candidate is a step of further outputting information representing
the degree of certainty about malignancy with respect to the pattern embedded in
the selected region (see column 36 lines 50-57.)

13.   Re claim 14 Nishikawa further discloses wherein the information representing
the degree of certainty about malignancy (i.e. likelihood of malignancy) is a
numerical value (see column 33 lines 13-25 column 36 lines 50-55.) Note that
likelihood of malignancy is disclosed as a numerical value.

14.   Re claim 15 Nishikawa further discloses wherein the information representing the

       degree of certainty about malignancy is a warning message, which is altered in

       accordance with the degree of certainty about malignancy (see column 33 lines 13-

       25 column 36 lines 50-55.) Note that likelihood of malignancy is disclosed as a

       numerical value, which is altered, based on the degree of likelihood of malignancy

       and thus constitutes a warning message.

15.   Re claim 16 Nishikawa further discloses wherein the medical image is a

       mammogram (see abstract.)

16.   Re claim 17 (see rejection for claim 13) Note in column 8 lines 9-34 and figure 2

       Nishikawa discloses computer system configured to perform the above method,

       which is a means for accomplishing the method.

17.   Re Claim 18-20, Claims 18-20 are rejected for the same reasons as Claims 14-

       16. Despite one set of claims being a method and one being a system the additional

       limitations added by these claims are the same. Therefore the prior art applied which

       teaches the method also teaches the corresponding systems.

Rejections Under 35 U.S.C. 103

       The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all

       obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

18.   Claim 1-2, 4-7, 10-12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Nishikawa US 6,058,332.

19.   Re Claim 1 Nishikawa discloses, an abnormal pattern candidate detection processing method, comprising the steps of: i) detecting an abnormal pattern candidate, which is embedded in a medical image, in accordance with a medical image signal representing a medical image, (see abstract) and ii) outputting at least information for specifying the detected abnormal pattern candidate (see abstract), wherein the method further comprises the step of calculating a degree of certainty about malignancy (i.e. likelihood of malignancy), which degree represents a level of possibility of a pattern being a malignant pattern, with respect to the abnormal pattern candidate (see column 33 lines 13-25), the calculation being made in accordance with an index value representing a feature of the abnormal pattern candidate and in accordance with a correlation between the index (i.e. ANN output) value and possibility of a pattern being a malignant pattern (see column 33 lines 13-25), which correlation has been obtained from clinical results (see column 33 lines 13-25.) Note the correlation depends on the probability distribution of malignant and benign cases. The step of outputting at least the information for specifying the detected abnormal pattern candidate is a step of outputting information representing

the degree of certainty about malignancy with respect to the abnormal pattern

candidate together with the information for specifying the detected abnormal pattern

candidate; (see column 36 lines 50-57) wherein the degree of certainty about

malignancy is determined from a single index value (Ann output column 33 line 13),

which is obtained by combining a plurality of indices (features see column 8 table 1)

representing a plurality of (feature measures features see table 1) of a calculation

object region (micro calcification cluster see column 8 table one).

20.   Nishikawa does not disclose a single index value which is obtained from a linear

combination of a plurality of indices. However, Nishikawa does suggests a well

known linear technique can be used instead of ANN (linear discriminate analysis see

column 20 lines 15-20) to achieve such a result. The results of such a combination

would be predictable. Therefore one or ordinary skill in the art would have found it

obvious to combine Nishikawa with linear discriminate analysis to reach the

aforementioned advantage.

21.   Re claim 2 Nishikawa discloses wherein the index value is an index (ANN output)

value utilized for the detection of the abnormal pattern candidate (candidate

abnormalities see abstract).

22.   Re claim 4 Nishikawa further discloses wherein the information representing the

degree of certainty about malignancy (i.e. likelihood of malignancy) is a numerical

value (see column 33 lines 13-25 column 36 lines 50-55.) Note that likelihood of

malignancy is disclosed as a numerical value.

23.   Re claim 5 Nishikawa further discloses wherein the information representing the

degree of certainty about malignancy is a warning message, which is altered in

accordance with the degree of certainty about malignancy (see column 33 lines 13-

25 column 36 lines 50-55.) Note that likelihood of malignancy is disclosed as a

numerical value, which is altered, based on the degree of likelihood of malignancy

and thus constitutes a warning message.

24.   Re claim 6 Nishikawa further discloses wherein the medical image is a

mammogram (see abstract.)

25.   Re claim 7 Nishikawa discloses, An abnormal pattern candidate detection

processing system, comprising: i) abnormal pattern candidate detecting means for

detecting an abnormal pattern candidate, which is embedded in a medical image, in

accordance with a medical image signal representing a medical image (see

abstract), and ii) image output means for outputting at least information for

specifying the detected abnormal pattern candidate (see abstract), wherein the

system further comprises malignancy certainty degree calculating means for

calculating a degree of certainty about malignancy (i.e. likelihood of malignancy),

which degree represents a level of possibility of a pattern being a malignant pattern,

with respect to the abnormal pattern candidate (see column 33 lines 13-25), the

calculation being made in accordance with an index (i.e. ANN output) value
representing a feature of the abnormal pattern candidate and in accordance with a
correlation between the index value and possibility of a pattern being a malignant
pattern (see column 33 lines 13-25.) The correlation has been obtained from clinical
results (see column 33 lines 13-25.) Note that the correlation depends on the
probability distribution of malignant and benign cases. The image output means
outputs information representing the degree of certainty about malignancy with
respect to the abnormal pattern candidate together with the information for
specifying the detected abnormal pattern candidate (see column 36, lines 50-57.)
Wherein the degree of certainty about malignancy is determined from a single index
value (Ann output column 33 line 13), which is obtained by combining a plurality of
indices (features see column 8 table 1) representing a plurality of (feature measures
features see table 1) of a calculation object region (micro calcification cluster see
column 8 table one). Note that in column 8, lines 9-34, and figure 2 Nishikawa
discloses a computer system "means" configured to perform the above method.

26.   Nishikawa does not disclose a single index value which is obtained from a linear
combination of a plurality of indices. However, Nishikawa does suggests a well
known linear technique can be used instead of ANN (linear discriminate analysis see
column 20 lines 15-20) to achieve such a result. The results of such a combination
would be predictable. Therefore one or ordinary skill in the art would have found it
obvious to combine Nishikawa with linear discriminate analysis to reach the
aforementioned advantage.

27.   Re Claim 8, 10-12, Claims 10-12 are rejected for the same reasons as Claims 2,

4-6. Despite one set of claims being a method and one being a system the additional

limitations added by these claims are the same. Therefore the prior art applied which

teaches the method also teaches the corresponding systems.

28.   Claim 1-2 and 7-8 are rejected under 35 U.S.C. 103(a) as being unpatentable

over Takeo USPGPUB 2002/0062075 in view of Cothren et al. US 6,154,560.

29.   Re claim 1,Takeo discloses an abnormal pattern candidate detection processing

method, comprising the steps of: i) detecting an abnormal pattern candidate, which

is embedded in a medical image, in accordance with a medical image signal

representing a medical image, (see abstract) and ii) outputting at least information

for specifying the detected abnormal pattern candidate (see abstract). Furthermore

Takeo discloses an index value representing a feature of the abnormal pattern

candidate, (see paragraph 22). Takeo also discloses a single index value

(Mahalanobis distance paragraph 29 and 33), which is obtained by combining a

plurality of indices (feature values paragraph 29) representing a plurality of feature

measures (feature values paragraph 29) of a calculation object region (prospective

shadow paragraph 29). Takeo does not disclose, wherein the method further

comprises the step of calculating a degree of certainty about malignancy (i.e.

likelihood of malignancy), which degree represents a level of possibility of a pattern being a malignant pattern, with respect to the abnormal pattern candidate, the calculation being made in accordance with an index value representing a feature of the abnormal pattern candidate and in accordance with a correlation between the index value and possibility of a pattern being a malignant pattern, which correlation has been obtained from clinical results, and the step of outputting at least the information for specifying the detected abnormal pattern candidate is a step of outputting information representing the degree of certainty about malignancy with respect to the abnormal pattern candidate together with the information for specifying the detected abnormal pattern candidate.

30.   Cothren discloses the idea of correlating determined values (ie index) to a probability (i.e. certainty) of malignancy wherein the method further comprises the step of calculating a degree of certainty about malignancy, which degree represents a level of possibility of a pattern being a malignant pattern with respect to the abnormal pattern candidate (see column 20 lines 60-67 column 21 lines 1-5.) Note that Cothren uses a look up table to calculate percent probability of malignancy. The calculation being made in accordance with an index value representing a feature of the abnormal pattern candidate and in accordance with a correlation between the index value (i.e. determined value) and possibility of a pattern being a malignant pattern (see column 20 lines 60-67 column 21 lines 1-5.) Note that Cothren describes a correlation between a determined value and probability of malignancy. Which correlation has been obtained from clinical results (see column 20 lines 58-

67.) Note the comparison is done with a distribution of empirical data. The step of outputting at least the information for specifying the detected abnormal pattern candidate is a step of outputting information representing the degree of certainty about malignancy with respect to the abnormal pattern candidate together with the information for specifying the detected abnormal pattern candidate (see column 20 lines 63-66.) One of ordinary skill in the art would readily recognize the advantage of having a probability of malignancy correlated to actual results because it is easier to interpret probability of malignancy then just a index value since the relative scale of the index value may not be known as described in therefore it would have been obvious to one of ordinary skill in the art to combine the present inventions to reach the aforementioned advantage.

31.   Re Claim 2 Takeo further discloses, wherein the index value is an index value utilized for the detection of the abnormal pattern candidate (see paragraph 22.) Note these "indices" are used for detection of the abnormal pattern candidate.

32.   Re Claim 7, Takeo in view of Wang also recites means for accomplishing each method step of claim 1. The previous rejection of claim 1 shows all of this function. Takeo further discloses, "In the abnormal shadow detection processing, the digital image signal is analyzed by a computer, which is Takeo's means for accomplishing this method(see paragraph 6.)

33.   Re claim 8, Claim 8 is rejected for the same reasons as claims 2. Despite one of

claim being a method and one being a system the additional limitations added by the

two claims are the same. Therefore the prior art applied which teaches the method

also teaches the corresponding systems.

34.   Claim 3, and 9 are rejected under 35 U.S.C. 103(a) as being unpatentable over

Nishikawa in view of Wang US 6,266,435.

35.   Re claim 3 Nishikawa discloses all of the steps of claim 1. Nishikawa does not

disclose, the mark displayed at the location of the abnormal patter candidate.

However Wang discloses wherein the information for specifying the detected

abnormal pattern candidate and the information representing the degree of certainty

about malignancy with respect to the abnormal pattern candidate are a mark (see

figure 2a and 2b and column 4 lines 23-27), which is displayed at a position for the

indication of the abnormal pattern candidate on the medical image (see figure 2a

and 2b), such that the kind of the mark may be altered in accordance with the

degree of certainty about malignancy (see column 4 lines 23-27.) Wang further

states with such an arrangement "a physician could efficiently allot his or her time in

assessing/dismissing the markers" (see column 8 lines 35-55.) Therefore one of

ordinary skill in the art would have found it obvious to combine the afore mentioned

features to reach the stated advantage.

36.   Re claim 9, Claim 9 is rejected for the same reasons as claim 3. Despite one of

claim being a method and one being a system the additional limitations added by the

two claims are the same. Therefore the prior art applied which teaches the method

also teaches the corresponding systems.

Allowable Subject matter

37.   Claim 21 - 24 are allowable. Nishikawa discloses an abnormal pattern candidate

detection processing method, comprising the steps of: i) detecting an abnormal

pattern candidate, which is embedded in a medical image, in accordance with a

medical image signal representing a medical image, and ii) outputting at least

information for specifying the detected abnormal pattern candidate, wherein the

method further comprises the steps of: a) calculating a degree of certainty about

malignancy, which degree represents a level of possibility of a pattern being a

malignant pattern, with respect to a predetermined region in the medical image,

which predetermined region has been set for each of pixels in the medical image, as

the degree of certainty about malignancy corresponding to each of the pixels in the

medical image, the calculation being made in accordance with an index value

representing a feature of a pattern embedded in the predetermined region and in

accordance with a correlation between the index value and possibility of a pattern

being a malignant pattern, which correlation has been obtained from clinical results.

(see rejection for claim 1.) Note the predetermined region is the entire image.

Nishikawa does not disclose, forming a distribution image signal representing a

distribution image, which represents a distribution of the degrees of certainty about malignancy in the medical image, in accordance with the thus calculated degrees of certainty about malignancy, each of which degrees corresponds to one of the pixels, and the step of outputting at least the information for specifying the detected abnormal pattern candidate is a step of further outputting the distribution image in accordance with the thus formed distribution image signal. Since this step is not taught by the prior art, claim 21 is allowable. Claim 22 is allowable because it depends from claim 21 Claims 23 and 34 recite similar subject matter to claims 22 and 21.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to SEAN MOTSINGER whose telephone number is (571)270-1237. The examiner can normally be reached on 9-5 M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bhavesh Mehta can be reached on (571)272-7453. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the

Patent Application Information Retrieval (PAIR) system. Status information for

published applications may be obtained from either Private PAIR or Public PAIR.

Status information for unpublished applications is available through Private PAIR only.

For more information about the PAIR system, see http://pair-direct.uspto.gov. Should

you have questions on access to the Private PAIR system, contact the Electronic

Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a

USPTO Customer Service Representative or access to the automated information

system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Motsinger
4/16/2008

 /Bhavesh M Mehta/

Supervisory Patent Examiner, Art Unit 2624